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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,017	12/12/2005	Maria Cristina Geroni	18086 (PC27339A)	9303

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

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12/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/533,017	GERONI ET AL.
	Examiner	Art Unit
	Meghan Finn	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,7 and 11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,7 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3, 5, 7, and 11-14 are presented for examination.

Applicant's Amendment filed November 8, 2007 has been received and entered into present application. Claims 2, 4, 6, and 8-10 were canceled and claims 11-14 were added by applicant. Thus claims 1, 3, 5, 7, and 11-14 are pending.

Applicants' arguments, filed November 8, 2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al. (Cytochrome P-450 and Other Determinants of Pharmacokinetics, Toxicity, and Efficacy in Humans) in view of Beulz-Riché et al. (Effects of paclitaxel, cyclophosphamide, ifosfamide, tamoxifen, and cyclosporine on the metabolism of methoxymorpholinodoxorubicin in human liver and microsomes), each already of record, for the reasons set forth at pages 7-8 of previous office action dated August 8, 2007, of which reasons are herein incorporated by reference.

Applicant argues that there is no motivation to combine the teaches of Collins et al. and Beulz-Riché et al. however, applicant fails to explain why it would not be common practice in cancer therapy to individualize dosages and/or why it would not be routine to use the test designed to optimize one drug on a similar drug that is also known to be metabolized by CYP3A. Rather, applicant argues that "the suggestion that structurally distinct compounds will act equivalently in medical practice is far removed

from reality. If it is generally accepted that chemical results cannot be predicted, it is axiomatic that this principle applies to drug treatment of patients."

It is true that the dosage determined by the methods of Collins et al. would not be expected to also be the correct dosage for a different drug such as nemorubicin as taught by Beulz-Riché et al., however that is neither what is being claimed or what was rejected in the previous office action. It would be obvious to use the system and principles of measuring CYP3A levels to optimize the dosage of a drug that is metabolized by CYP3A. It is expected that the structurally distinct drugs would act differently, however since they are both metabolized by CYP3A, both drugs should be affected by the levels and the principle of measuring those levels to optimize would be expected to apply to two structurally distinct compounds.

This argument is not deemed persuasive and thus the rejection of claims 1, 3, 5, and 7 is **maintained.**

Claim Rejections - 35 USC § 103 (New grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al. (Cytochrome P-450 and Other Determinants of Pharmacokinetics, Toxicity,

and Efficacy in Humans) in view of Beulz-Riché et al. (Effects of paclitaxel, cyclophosphamide, ifosfamide, tamoxifen, and cyclosporine on the metabolism of methoxymorpholinodoxorubicin in human liver and microsomes), each already of record in office action dated August 8, 2007, which is incorporated by reference. Since claims 11-14 are newly added, there is no existing rejection on record and a new grounds of rejection is necessitated by amendment.

Claims 11-14 depend on claims 1, 3, 5, and 7 respectively. In each case the method of detecting CYP3A levels is further specified to occur by an erythromycin breath test (ERMBT). Since ERMBT is used by Collins et al. to measure the CYP3A levels as discussed above and in the previous office action dated August 8, 2007, it would have been obvious to use the test of Collins et al. (including using ERMBT) to optimize the dosages of nemorubicin as taught by Beulz-Riché et al. Thus claims 11-14 are unpatentable over Collins et al. in view of Beulz-Riché et al.

Conclusion

Rejection of claims 1, 3, 5, and 7 is deemed proper and is **maintained.** A new grounds of rejection of claims 11-14 is necessitated by amendment and thus is made **FINAL**.

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

12/3/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER